

EXHIBIT 243

MODEL LETTER ANNOUNCING TO A CLIA-EXEMPT LABORATORY THAT IT IS IN COMPLIANCE WITH THE CLIA CONDITIONS AFTER A SAMPLE VALIDATION OR SUBSTANTIAL ALLEGATION OF NONCOMPLIANCE SURVEY

(Date)

CLIA Director Name

Name of Laboratory

Address

City, State, ZIP Code

Dear **(Laboratory Director)**:

RE: CLIA Number **(CLIA Number)**

I am pleased to inform you that as a result of the Centers for Medicare & Medicaid Services' (CMS) **(sample validation, complaint)** survey, the **(name of laboratory)** was found to be in compliance with the Clinical Laboratory Improvement Amendments of 1988 (CLIA) Conditions.

The CMS surveyors advised you, however, of other deficiencies noted during the **(sample validation, complaint)** survey of your laboratory, and we are enclosing a listing of all deficiencies found by them. We have forwarded a copy of this letter and our findings from the survey **(optional -- and your plan and timetable for correcting the deficiencies cited)** to the State agency for further action. The **(State agency)** will be in touch with you to discuss the survey findings and to monitor the correction of the deficiencies.

Under Federal disclosure rules, a copy of the findings of this survey must be publicly disclosed within 90 days of the completion of the survey. You may therefore wish to submit for public disclosure, if you have not already done so, your comments on the survey findings, and any plans you may have for correcting the cited deficiencies.

(Name)

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(Date)

We thank you for your cooperation.

Sincerely yours,

Associate Regional Administrator
(or its equivalent)

Enclosure(s)

cc: Central Office